

Standard Operating Procedure for Development of New Study Questionnaires and REDCap database

Standard Operating Procedure for Modifications to Current Study Questionnaires and Associated REDCap updates

Version Date: 21/7/2022

POLICY:

The protocol for the development of new study questionnaires and creation of associated REDCap databases is outlined below. The protocol for making modifications to existing, actively in-use study questionnaires and associated REDCap updates is also outlined below. These steps are critical for the success of all ARGO studies. All sites are responsible for ensuring adherence to the outlined protocol. If there are any questions, please reach out to the OAU ARGO manager Dr. Israel Owoade: Israeladeyemigmi@gmail.com or MSKCC ARGO Research Team, Cristina Olcese: OlceseC@mskcc.org or Rivka Kahn: kahn1@mskcc.org.

PROCEDURE: *New Study Questionnaires + REDCap*

1. Once the questionnaire is developed for a new study, it will be reviewed by key stakeholders. This will entail a multi-level review process including but not limited to the following:
 - a. Principal Investigator
 - b. Research Project Manager
 - c. Research Assistants/Community Health Workers (as applicable)
2. The PI of such a study must make his/her intention known to the ARGO REDCap Administrator through the National Principal Investigator. The National Principal Investigator will decide whether to approve the study



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and/or request a fee for the mobilization of ARGO REDCap resources towards the project.

3. PI then submits a completed ARGO REDCap study initiation request form to ARGO REDCap administrators: Matteo di Bernardo: md3498@columbia.edu and Akintayo Taiwo: akintayotaiwo.olaniyan@gmail.com. The REDCap administrators will provide an estimated timeline for REDCap database build upon receipt of all required study documents. *Please see separate **ARGO REDCap Study Initiation Request Form** on ARGO Website and **REDCap Manual Section B: Steps for developing a REDCap Database**. <https://www.argo-research.org/REDCap-manual-and-SOPs/>*
4. The new questionnaire and REDCap database will be piloted/field tested with first 5 patients accrued on study. If any changes are needed, this will be communicated with the ARGO REDCap administrators.

PROCEDURE: Modifications to Current Study Questionnaires + REDCap

1. If the PI would like to make modifications to a current study questionnaire + REDCap, PI will present the proposed changes at an ARGO joint meeting for review and approval. (If PI is unable to present at a joint meeting due to timing, the PI will forward the request and detailed explanation to Dr. Peter Kingham (kinghamp@mskcc.org) and Professor Isaac Alatisé (segunalatishe@gmail.com) for review.
2. Once approval is received from Dr. Kingham and Professor Alatisé, PI will send modification request with documented approval attached to the REDCap ARGO administrators: Taiwo and Matteo. *Please see **REDCap Manual Section B7: Modifying REDCap Database on ARGO Website for more detailed explanation of required steps to modify questionnaires and REDCap database**. <https://www.argo-research.org/REDCap-manual-and-SOPs/>*
3. The updated questionnaire and REDCap will be piloted for the first 5 patients. If any changes are needed, this will be communicated with the ARGO REDCap administrators.



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It is imperative that no changes are made to any questionnaires or any REDCap database on any ARGO studies prior to receiving approval from Dr. Peter Kingham and Professor Isaac Alatise.

Revision History

Revision #	Effective Date	Changes